

### **REMARKS**

This is in response to the Office Action dated September 21, 2004, in which Claims 1-5 and 10-22 were rejected under 35 U.S.C. 102(b) as being anticipated by Berger (4,574,084) and Claims 6-9, 22-26 and 32-35 were rejected under 35 U.S.C. 103(a) as being unpatentable over Berger (4,574,084). The Office Action further rejected Claims 19-31 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 and 2 of U.S. Patent No. 6,592,907. The rejections over Claims 1-26 and 32-35 are respectfully traversed based on the following remarks. A terminal disclaimer in compliance with 37 CFR 1.321 is respectfully submitted to overcome the obviousness-type double patenting rejection over Claims 19-31. Therefore, as respectfully submitted, all the pending claims are patentable.

#### ***The Cited Reference***

**Berger – U.S. 4,574,084**

##### **1. Berger fails to teach 0.001 wt. % to 0.05 wt. % of the peroxy compound**

In col. 2, lines 65-67, Berger discloses “This more particularly applies with a 0.001 to 0.01 **molar concentration** of the peroxy compound in the **greenish finished solution**”. Further in col. 2, lines 24-29, Berger teaches that the greenish finished solution is the chlorite solution containing the peroxy compound. It is well known in the art that the molar concentration of the peroxy compound is the number of moles of the peroxy compound per liter of the chlorite solution.

The molar concentration of 0.001 to 0.01 does not indicate a weight percentage of 0.001 to 0.01. A simple calculation can be easily performed to derive the approximate weight percentage of the molar concentration of 0.001 to 0.01 for peroxy compound. Assuming the density of the chlorite solution is 1 g/cm<sup>3</sup> (which is the density of pure water); and therefore, the weight of one liter of the chlorite solution is 1000 grams. The molecular weight of peroxy compound (H<sub>2</sub>O<sub>2</sub>, for example) is 34 gram/mol, such that the weight of 0.001 to 0.01 moles of peroxy compound is 0.034 g to 0.34g. The weight percentage of the peroxy compound is thus equal to 0.034/1000 to 0.34/1000, which is 0.000034 wt. % to

0.00034 wt. %. This is far less than the range of 0.001 wt. % to 0.05 wt. %. Even the density of the chlorite solution may vary from 1 g/cm<sup>3</sup>, the variation in density does not appear large enough to result in the weight percentage as much as 0.001 wt. % for peroxy compound.

**2. Berger teaches away “the chlorite composition remains intact without degrading the chlorite compound into chlorine dioxide during storage at about a room temperature”.**

According to above, Berger does not teach the weight percentage as claimed in the current application. Therefore, the chlorite solution disclosed by Berger is not the same as the composition as claimed in the current application. Further, in col. 6, lines 27-30, Berger specifically discloses “The finished solution **generally contains 8 to 15% by weight of chlorine dioxide, the range 10 to 12% by weight being regularly particularly advantageous.**” Therefore, Berger actually teaches away that the chlorite composition remains intact without degrading the chlorite compound into chlorine dioxide as claimed.

Danner et al. – U.S. Patent No. 5,855,922

**1. Danner et al. does not teach the composition remains “intact” without degrading the chlorite compound into chlorine dioxide**

Danner et al. teaches metal chlorites in such a manner as to **suppress** the production of chlorine dioxide. It is understood that the suppression of chlorine dioxide simply indicates reduction in chlorine dioxide. There is no suggestion that the metal chlorites should be **intact** without degrading the chlorite compound into chlorine dioxide.

**2. Danner et al. does not teach use of “lubricant”, nor the composition comprising the lubricant**

Danner et al. teaches the composition may be applied **in conjunction with** a gel application medium to adhere the metal chlorite to the skin; however, there is no suggestion or motivation the gel being comprised by the composition. In addition, the teaching of use of gel does not explicitly or inherently teaches the use of lubricants. Further, although Danner et al. teaches that cellulose gels, particular methyl, hydroxymethyl and hydroxyethyl cellulose gels, polyvinylsulfonic acid, polyamide and silica-base gels are preferred, Danner et al. does not teach any of these gels are “non-ionic, anionic or a combination thereof”.

***Rejection Under 35 U.S.C. 102(b)***

Claims 1-5 and 10-22 were rejected under 35 U.S.C. 102(b) as being anticipated by Berger (4,574,084). The Examiner relied on column 2, line 66, column 3, lines 61-63, column 7, lines 66-68 and claims 4 and 5 of Berger as the teaching of the use of sodium chlorite and hydrogen peroxide at the claimed concentration and PH as antibacterial composition. The Examiner further contended that the lack of degradation of chlorite compound to chlorine is considered to be the inherent property of such composition.

The rejections over Claims 1-5 and 10-22 are respectfully traversed.

As discussed above, Berger teaches concentration of hydrogen peroxide to be 0.001 to 0.01 molar concentration, which means that every liter of the composition (the chlorite solution) contains 0.001 to 0.01 mole of hydrogen peroxide. This results in a weight percentage of hydrogen peroxide far less than 0.001 wt. % to 0.05 wt. % as claimed in Claims 1-35.

Further, Berger specifically emphasizes the advantages of producing chlorine dioxide from chlorite in col. 6, lines 21-30. This is contradictory to the Examiner's rationale that considers "lack of degradation of chlorite compound to chlorine" as an inherent property of the chlorite solution disclosed by Berger.

Therefore, Berger does not only fail to teach the weight percentage of the hydrogen peroxy contained in the composition, but teaches away from a composition remaining intact without degrading the chlorite compound into chloride dioxide during storage at about a room temperature as claimed in Claims 1-35. Therefore, the rejections over Claims 1-5 and 10-22 are respectfully traversed.

In Claims 10-14 and 27-31, the present application further discloses the composition being a liquid ophthalmic composition for providing the therapeutic application onto an eye of a living being. As discussed above, the chlorite solution provided by Berger is mainly used for biocide, which is known as a pesticide that is harmful to living beings. Although Berger also discloses applying the chlorite solution to drinking water and skin, none of the applications appears to be feasible or applicable to direction application to eyes of living beings.

***Rejection Under 35 U.S.C. 103(a)***

Claims 6-9 and 22-26 and 32-35 were rejected under 35 U.S.C. 103(a) as being unpatentable over Berger and Danner et al. The Examiner admits that Berfer differs from Claims 6-9 and 22-26 and 32-35 in the use of the secondary components, such as polymers and buffers. The Examiner relied upon Danner et al. for the teaching of suppressing the production of chlorine dioxide and the addition of polymers to a metal chlorite for forming a gel.

As discussed, Berger does not only fail to teach the weight concentration of peroxy compound as claimed, but also fails to teach the composition being intact without degrading the chlorite compound into chlorine dioxide during storage at room temperature. Danner et al. does not teach the composition containing peroxy compound at all.

Danner et al. teaches using metal chlorites in such a manner as to suppress the production of chlorine dioxide (col. 5, lines 51-54). As understood, the manner to suppress the production of chlorine dioxide does not explicitly or inherently teach the composition remaining intact without degrading the chlorine dioxide.

Further, in col. 6, lines 58-66 that the Examiner relied upon for the teaching of lubricant comprised by the composition, Danner et al. teaches "*For use on human or animal skin, the compositions may be typically applied in conjunction with a gel application medium because of the ability of the gel to adhere to the skin. Any gelling agent or thickener which is non-toxic and nonactive with the metal chlorite may be used. Cellulose gels, polyvinylsulfonic acid, polyamide and silica-base gels are preferred.*"

Firstly, what is disclosed is the use of gel, not the use of lubricant. The teaching of gel does not explicitly or inherently teach the use of lubricant. Secondly, the above disclosure only teaches the composition to be applied to skin in conjunction with gel, but fails to teach the composition comprising a gel. On the contrary, it appears that the gel is not comprised by the composition. Thirdly, Danner et al. fails to teach any of the chemical compound being non-ionic, anionic or a combination thereof as claimed in Claims 6-10 and 23-26.

Regarding Claims 10 and 26, Danner further fails to disclose hyaluronic acid with about 0.001 wt. % to about 0.5 wt. %.

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As such, it is respectfully submitted that Berger and Danner et al., individually or in combination, fail to teach every element as claimed, and a *prima facie* case of obviousness is not established. The rejection over Claims 6-9 and 22-26 and 32-35 is respectfully traversed.

***The Rejection Under Judicially Double-Patenting Obviousness***

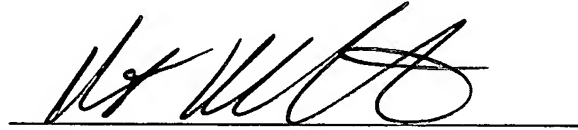
A terminal disclaimer is respectfully submitted as attached. Therefore, Claims 19-31 are believed patentable.

If any additional fee is required, please charge Deposit Account Number 19-4330.

Respectfully submitted,

Date: 2/15/05

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